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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,671	08/20/2003	Anthony J. Coyle	MPI00-212CP1CN1M	6437

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MILLENNIUM PHARMACEUTICALS, INC.  
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CAMBRIDGE, MA 02139

EXAMINER
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OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/644,671	Applicant(s) COYLE ET AL.	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

1. Claims 1 – 23 are pending.
2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.
3. The instant claims contain recitations of multiple amino acid and nucleic acid sequences. These molecules are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

It is further noted that the instant claims include a recitation of a "compound which selectively binds to a polypeptide," while the respective dependent claims recite a compound which is an antibody. In the event that additional (non-antibody) types of compounds selectively binding the polypeptides of the invention are introduced into the claims during prosecution, additional restriction and/or species election may be required.

For restriction purposes it is assumed that ATCC deposit No. 2084 corresponds to nucleic acid of SEQ ID NO:1 and polypeptide of SEQ ID NO:2, and ATCC deposit No. 2085 corresponds to nucleic acid of SEQ ID NO:3 and polypeptide of SEQ ID NO:4. If this assumption is incorrect, Applicant is invited to clarify the relationship between the ATCC deposits and the corresponding sequences.

***Restriction Requirement***

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 – 7 and 12 – 13, drawn to a nucleic acid molecule encoding human B7-H2, specifically SEQ ID NO:1 or 3, or deposited with ATCC under Accession Number 2084 or 2085, or encoding a polypeptide of SEQ ID NO:2 or 4, as well as vectors, host cells, methods of producing the polypeptide, and kits comprising the nucleic acids, classified in Class 536, subclass 23.5, and Class 435, subclasses 320.1, 455, 69.1, and 810.

II. Claims 1 – 7 and 12 – 13, drawn to a nucleic acid molecule encoding mouse B7-H2, specifically SEQ ID NO:30, or encoding a polypeptide of SEQ ID NO:31, as well as vectors, host cells, methods of producing the polypeptide, and kits comprising the nucleic acids, classified in Class 536, subclass 23.5, and Class 435, subclasses 320.1, 455, 69.1, and 810.

III. Claims 8 – 10, drawn to a human B7-H2 polypeptide, specifically SEQ ID NO:2 or 4, or encoded by nucleic acids of SEQ ID NO:1 or 3, or deposited with ATCC under Accession Number 2084 or 2085, classified in Class 530, subclass 350.

IV. Claims 8 – 10, drawn to a mouse B7-H2 polypeptide, specifically SEQ ID NO:31, or encoded by nucleic acids of SEQ ID NO:30, classified in Class 530, subclass 350.

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V. Claims 11 and 16, drawn to an antibody which selectively binds a human B7-H2 polypeptide, and a kit comprising the antibody, classified in Class 530, subclass 387.1, and Class 435, subclass 810.

VI. Claims 11 and 16, drawn to an antibody which selectively binds a mouse B7-H2 polypeptide, and a kit comprising the antibody, classified in Class 530, subclass 387.1, and Class 435, subclass 810.

VII. Claims 14 and 15, drawn to a method for detecting the presence of a human B7-H2 polypeptide by contacting the sample with an antibody, classified in Class 435, subclass 7.1.

VIII. Claims 14 and 15, drawn to a method for detecting the presence of a mouse B7-H2 polypeptide by contacting the sample with an antibody, classified in Class 435, subclass 7.1.

IX. Claims 17 and 18, drawn to a method for detecting the presence of a nucleic acid encoding human B7-H2 by contacting the sample with a nucleic acid probe, classified in Class 435, subclass 6.

X. Claims 17 and 18, drawn to a method for detecting the presence of a nucleic acid encoding mouse B7-H2 by contacting the sample with a nucleic acid probe, classified in Class 435, subclass 6.

XI. Claims 20 and 21, drawn to a method for identifying a compound which binds to a human B7-H2 polypeptide, classified in Class 435, subclass 7.1.

XII. Claims 20 and 21, drawn to a method for identifying a compound which binds to a mouse B7-H2 polypeptide, classified in Class 435, subclass 7.1.

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XIII. Claim 22, drawn to a method for modulating the activity of a human B7-H2 polypeptide, classified in Class 435, subclass 375.

XIV. Claim 22, drawn to a method for modulating the activity of a mouse B7-H2 polypeptide, classified in Class 435, subclass 375.

XV. Claim 23, drawn to a method for identifying a compound which modulates the activity of a human B7-H2 polypeptide, classified in Class 435, subclass 7.1.

XVI. Claim 23, drawn to a method for identifying a compound which modulates the activity of a mouse B7-H2 polypeptide, classified in Class 435, subclass 7.1.

5. Groups I - VI are different products. The products are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each product is patentably distinct, and searching of these Inventions would impose an undue burden.

Groups VII – XVI are different methods. The methods differ with respect to one or more of ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

Groups (I, II) and (IX, X); (III, IV) and (XI – XVI); and (V, VI) and (VII, VIII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

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claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid molecules of Groups I and II can be used for PCR amplification; the polypeptides of Groups III and IV can be used for raising antibodies, and antibodies of Groups V and VI can be used for affinity purification, in addition to the methods recited.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### ***Species Election***

7. This application contains claims directed to the following patentably distinct Species of the claimed Inventions I, III, V, VII, IX, XI, XIII, and XV, wherein the human B7-H2 is:

- A. the long form (SEQ ID NO: 2, or ATCC deposit No. 2084), or
- B. the short form (SEQ ID NO:4, or ATCC deposit No. 2085).

These species are distinct because their structures and physicochemical properties and mode of action are different, and the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise*



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*include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

November 29, 2005

*Phillip Gambel*

PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER

*Ben Carter*

*11/29/05*